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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/608,671	06/27/2003	Michael J. Pugia	MSA-3452	5201

7590 12/08/2004
Elizabeth A. Levy
Bayer HealthCare LLC
63 North Street
Medfield, MA 02052

EXAMINER

SINES, BRIAN J

ART UNIT	PAPER NUMBER
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1743

DATE MAILED: 12/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/608,671

Applicant(s)

PUGIA ET AL.

Examiner

Brian J. Sines

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11/30/2004 (*Interview Summary*).
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) 11-13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 6/27/2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of group I comprising claims 1 – 10 as indicated in the interview summary for 11/30/2004 is acknowledged. Claims 11 – 13 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, each of the claimed features, such as the capillary passageway, posts, and the grooves or weirs containing wedge-shaped cut-out structures, etc., must be shown and clearly labeled or the feature(s) canceled from the claim(s). Furthermore, with regard to figure 5, it is unclear as to how sample fluid is transferred from port 10 to prechamber 12 via capillary action, since the figure does not appear to indicate a fluidic connection, such as a channel, connecting these two features. No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency.

Additional replacement sheets may be necessary to show the renumbering of the remaining figures. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

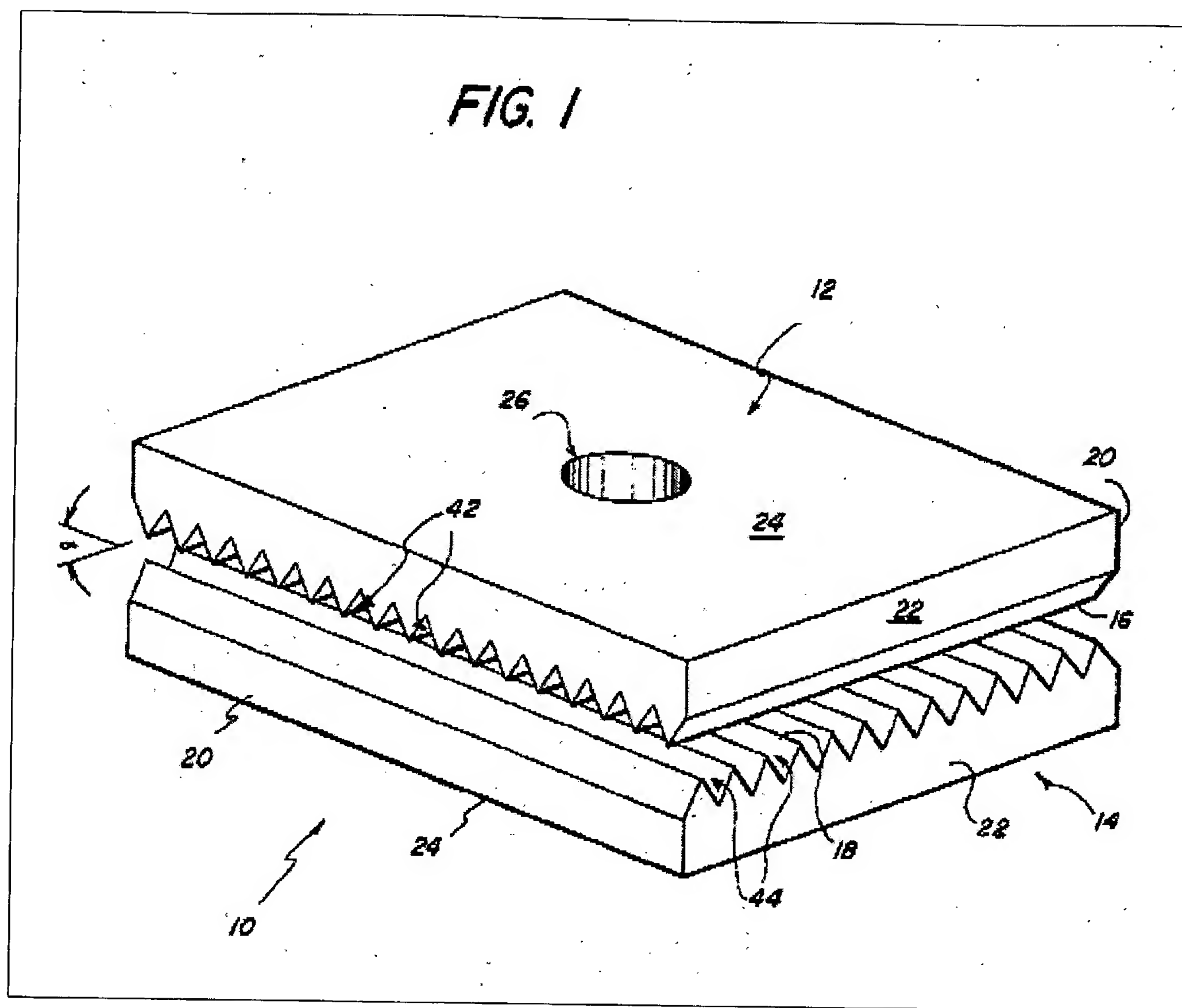
Claim Rejections - 35 USC § 102

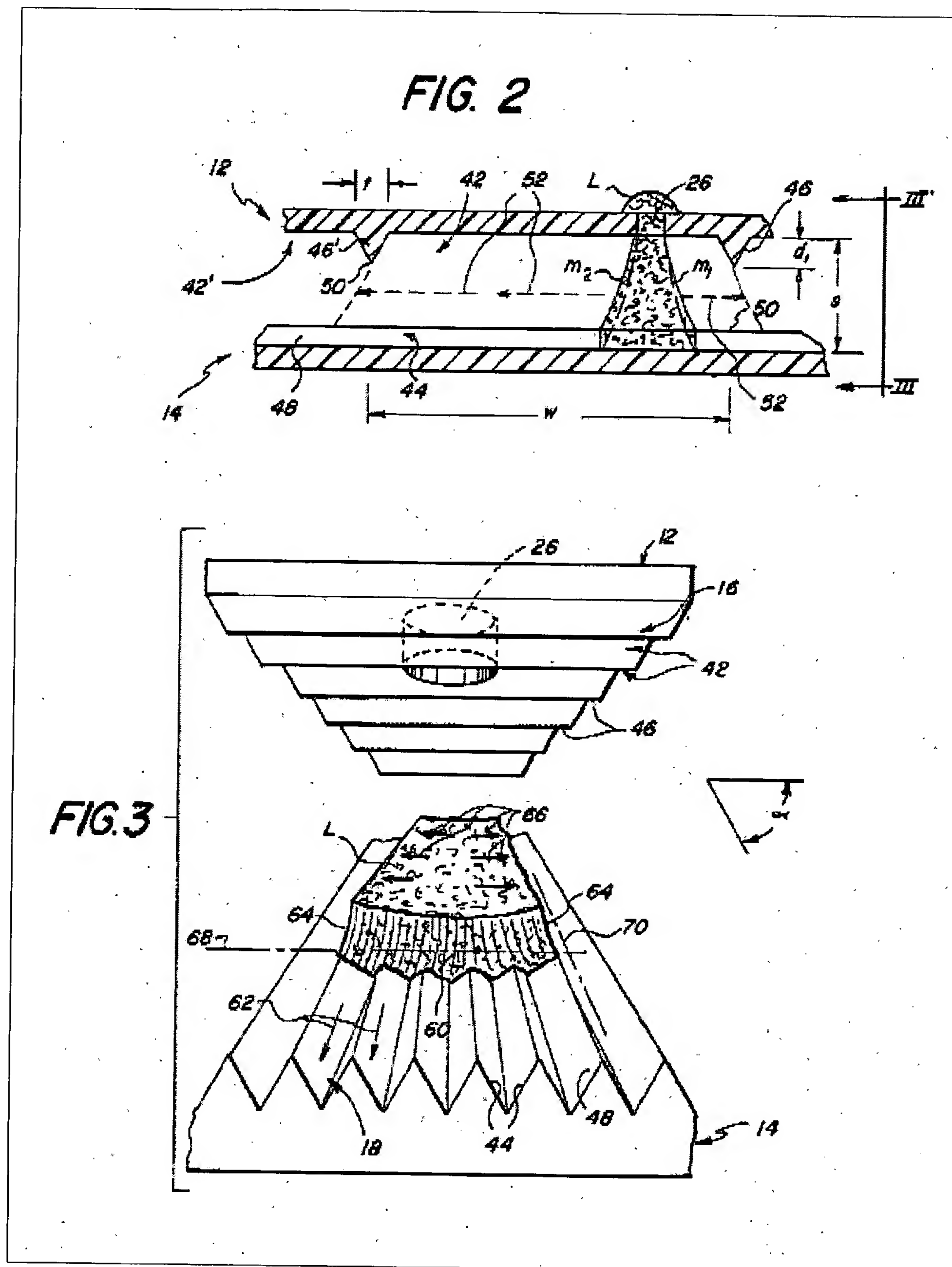
The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

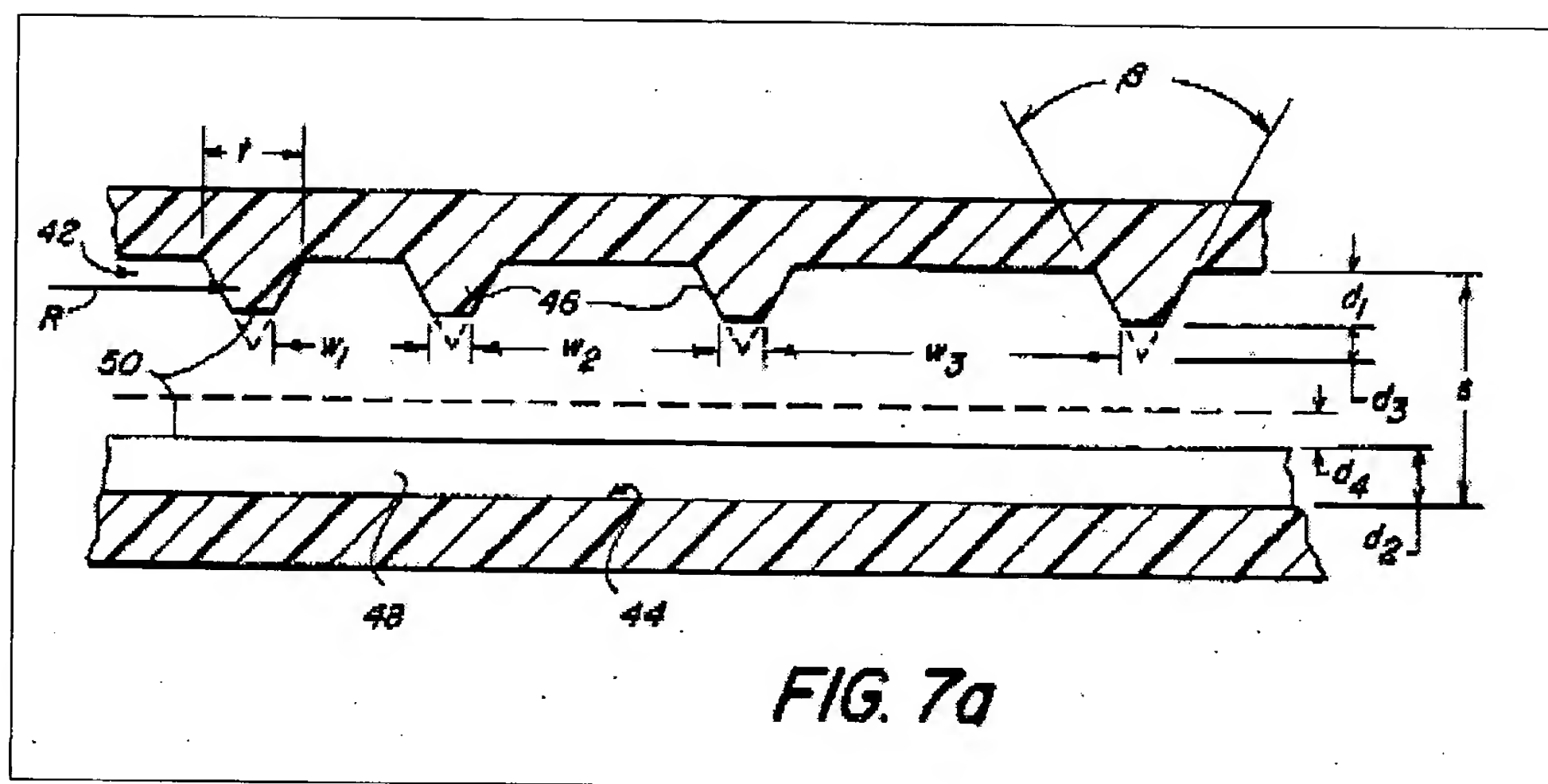
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1 – 3 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Columbus (U.S. Pat. No. 4,233,029). Regarding claims 1 and 2, Columbus '029 teaches a microfluidic apparatus (10) comprising: an inlet port (aperture 26); a capillary passageway (e.g., the sidewalls of the inlet port 26 extending through top member 12) in fluid communication with the inlet port (26); an inlet chamber (e.g., the spacing between interior surfaces 16 & 18) in fluid communication with the capillary passageway, wherein the inlet chamber comprises means (grooves 42 & 44) for uniformly distributing sample fluid across the chamber and displacing air from the chamber; and at least one vent passageway (e.g., the space between members 12 & 14 left exposed at either edge 20 or 22) (see col. 1, line 1 – col. 6, line 60; figures 1 – 3).





Regarding claim 3, as shown in figure 7a, Columbus '029 further teaches the incorporation of weir structures (truncated ridges 46) within the apparatus (see col. 8, lines 1 – 51).

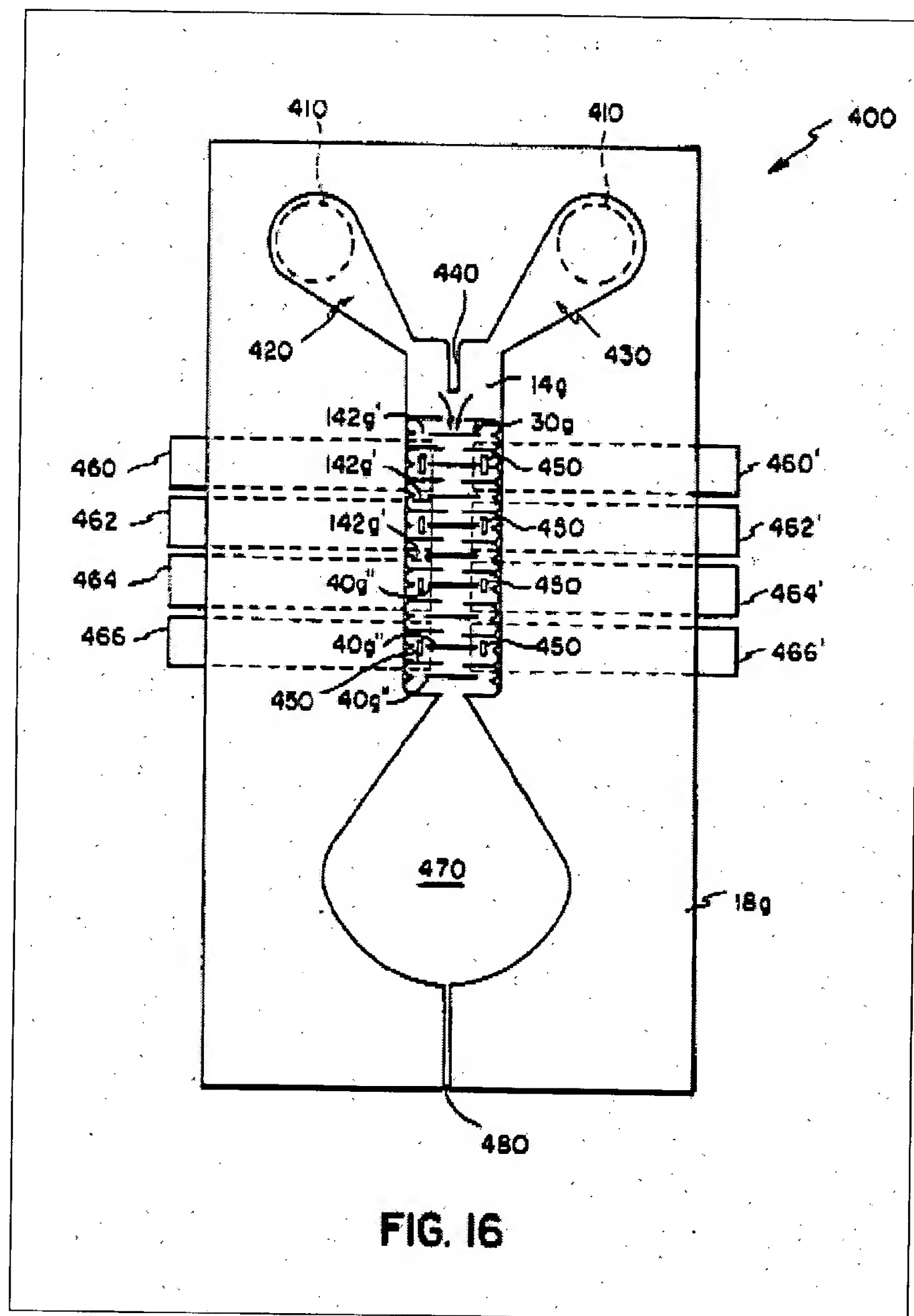


Regarding claim 8, the recitation that a blood anti-coagulant is deposited in the inlet chamber is considered a process or intended use limitation, which does not further delineate the structure of the claimed apparatus from that of the prior art. Since these claims are drawn to an apparatus statutory class of invention, it is the structural limitations of the apparatus, as recited in the claims, which are considered in determining the patentability of the apparatus itself. Process or intended use limitations are accorded no patentable weight to an apparatus. Process limitations do not add patentability to a structure, which is not distinguished from the prior art. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967); and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). The Courts have held that it is well settled that the recitation of a new intended use, for an old product, does not make a claim to that old product patentable. See *In re Schreiber*, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1431

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(Fed. Cir. 1997). The Courts have held that the manner of operating an apparatus does not differentiate an apparatus claim from the prior art, if the prior art apparatus teaches all of the structural limitations of the claim. See *Ex Parte Masham*, 2 USPQ2d 1647 (BPAI 1987). Furthermore, the Courts have held that apparatus claims must be structurally distinguishable from the prior art in terms of structure, not function. See *In re Danley*, 120 USPQ 528, 531 (CCPA 1959); and *Hewlett-Packard Co. V. Bausch and Lomb, Inc.*, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990) (see MPEP § 2114).

2. Claims 1 – 3 and 8 – 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Columbus (U.S. Pat. No. 4,618,476). Regarding claims 1 and 3, as shown in figure 16, Columbus '476 teaches a microfluidic apparatus (multiple test element 400) comprising: an inlet port (inlet aperture 410); a capillary passageway (liquid delivery capillary zones 420 & 430) in fluid communication with the inlet port (410); an inlet chamber (capillary transport zone 30g) in fluid communication with the capillary passageway (420 & 430), wherein the inlet chamber comprises means (e.g., rib structures 40g", which are structurally equivalent to a weir structure) for uniformly distributing sample fluid across the chamber and displacing air from the chamber; and at least one vent passageway (vent aperture 480) (see col. 7, lines 15 – 64; figure 16). Regarding claim 2, Columbus '476 teach the incorporation of groove or slot structures (142g') within the apparatus.



Regarding claim 9, Columbus '476 teaches the incorporation of an overflow cavity or chamber (470) within the apparatus.

Regarding claim 8, the recitation that a blood anti-coagulant is deposited in the inlet chamber is considered a process or intended use limitation, which does not further delineate the structure of the claimed apparatus from that of the prior art. In addition, with respect to claim 10, the recitation that the overflow chamber contains an indicator,

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such as an indicator reagent, as disclosed by the applicants specification, is also considered a process or intended use limitation. Since these claims are drawn to an apparatus statutory class of invention, it is the structural limitations of the apparatus, as recited in the claims, which are considered in determining the patentability of the apparatus itself. Process or intended use limitations are accorded no patentable weight to an apparatus. Process limitations do not add patentability to a structure, which is not distinguished from the prior art. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967); and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). The Courts have held that it is well settled that the recitation of a new intended use, for an old product, does not make a claim to that old product patentable. See *In re Schreiber*, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1431 (Fed. Cir. 1997). The Courts have held that the manner of operating an apparatus does not differentiate an apparatus claim from the prior art, if the prior art apparatus teaches all of the structural limitations of the claim. See *Ex Parte Masham*, 2 USPQ2d 1647 (BPAI 1987). Furthermore, the Courts have held that apparatus claims must be structurally distinguishable from the prior art in terms of structure, not function. See *In re Danley*, 120 USPQ 528, 531 (CCPA 1959); and *Hewlett-Packard Co. V. Bausch and Lomb, Inc.*, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990) (see MPEP § 2114).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
1. Claims 4 – 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Columbus '029 in view of Peters (U.S. Pat. No. 6,296,126 B1). Regarding claim 4, Columbus '029 is silent to the specific teaching of incorporating wedge-shaped cut-out structures with the microfluidic apparatus. As shown in figure 3b, Peters does teach the incorporation of wedge-shaped cut-out structures (columnar projection 9 having wedge-shaped cut-outs 1) within a microfluidic apparatus for facilitating effective fluid control within a microfluidic device (see col. 1, line 10 – col. 6, line 67; figures 1a, 3b & 4).

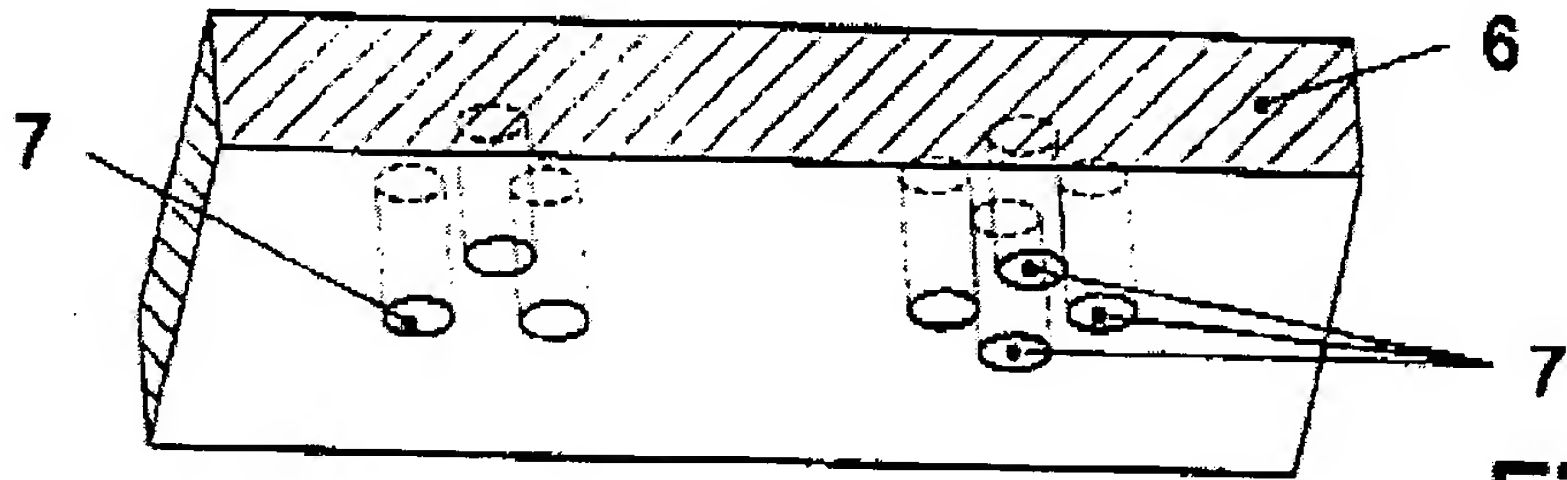


Fig. 3a

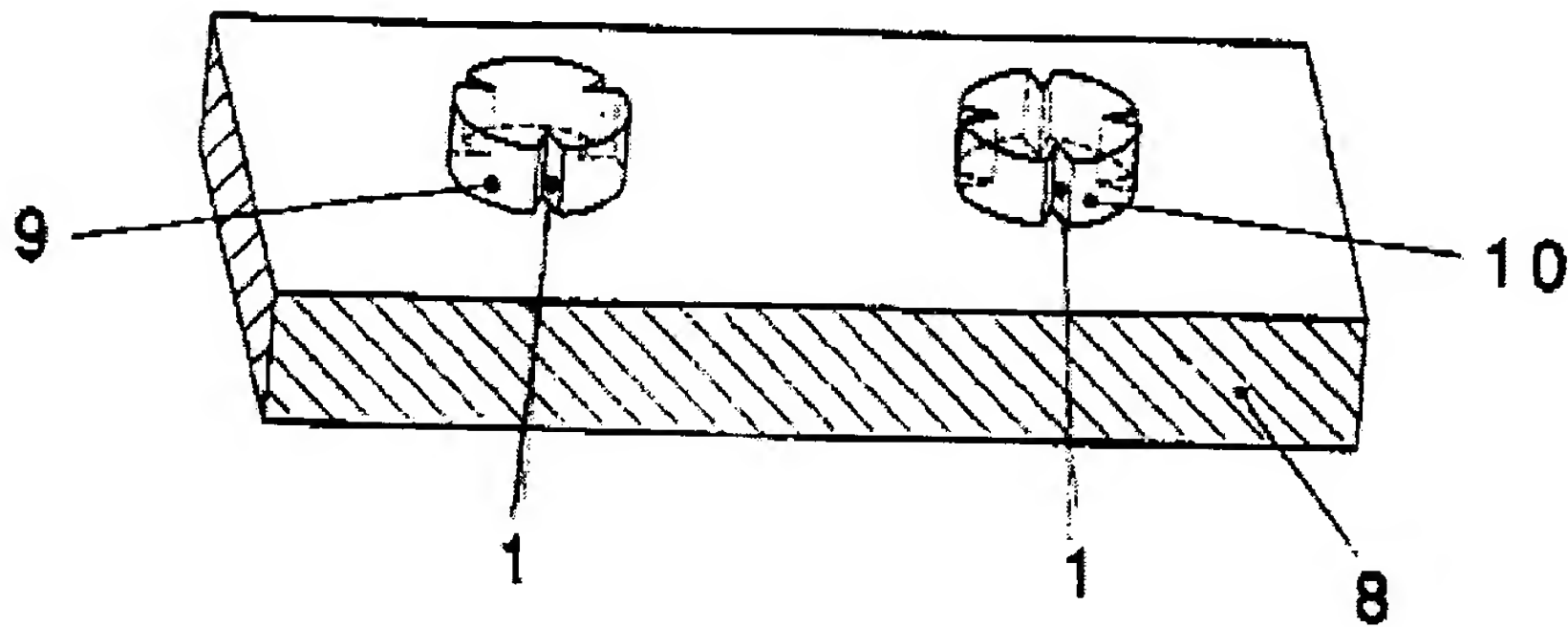


Fig. 3b

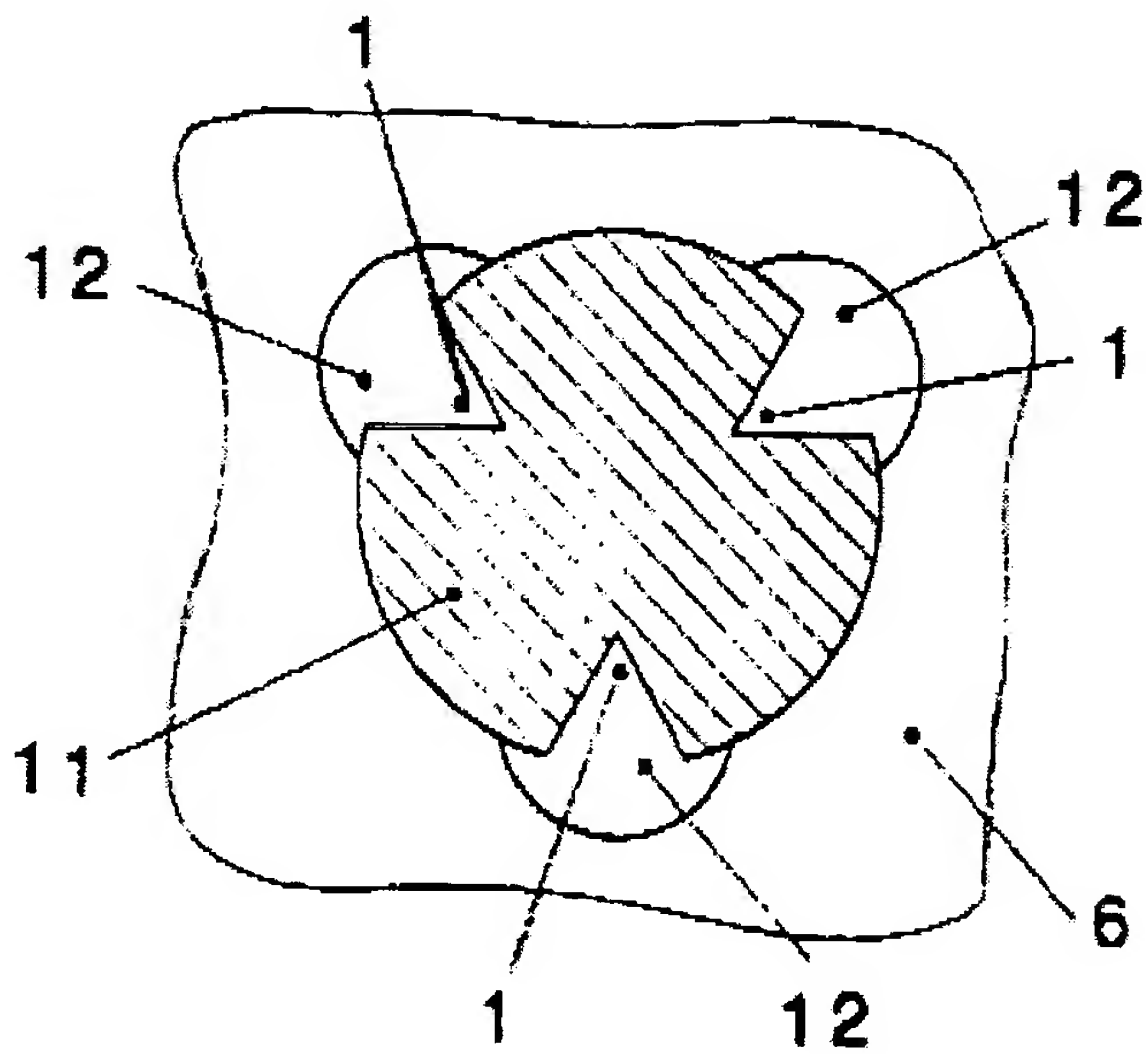


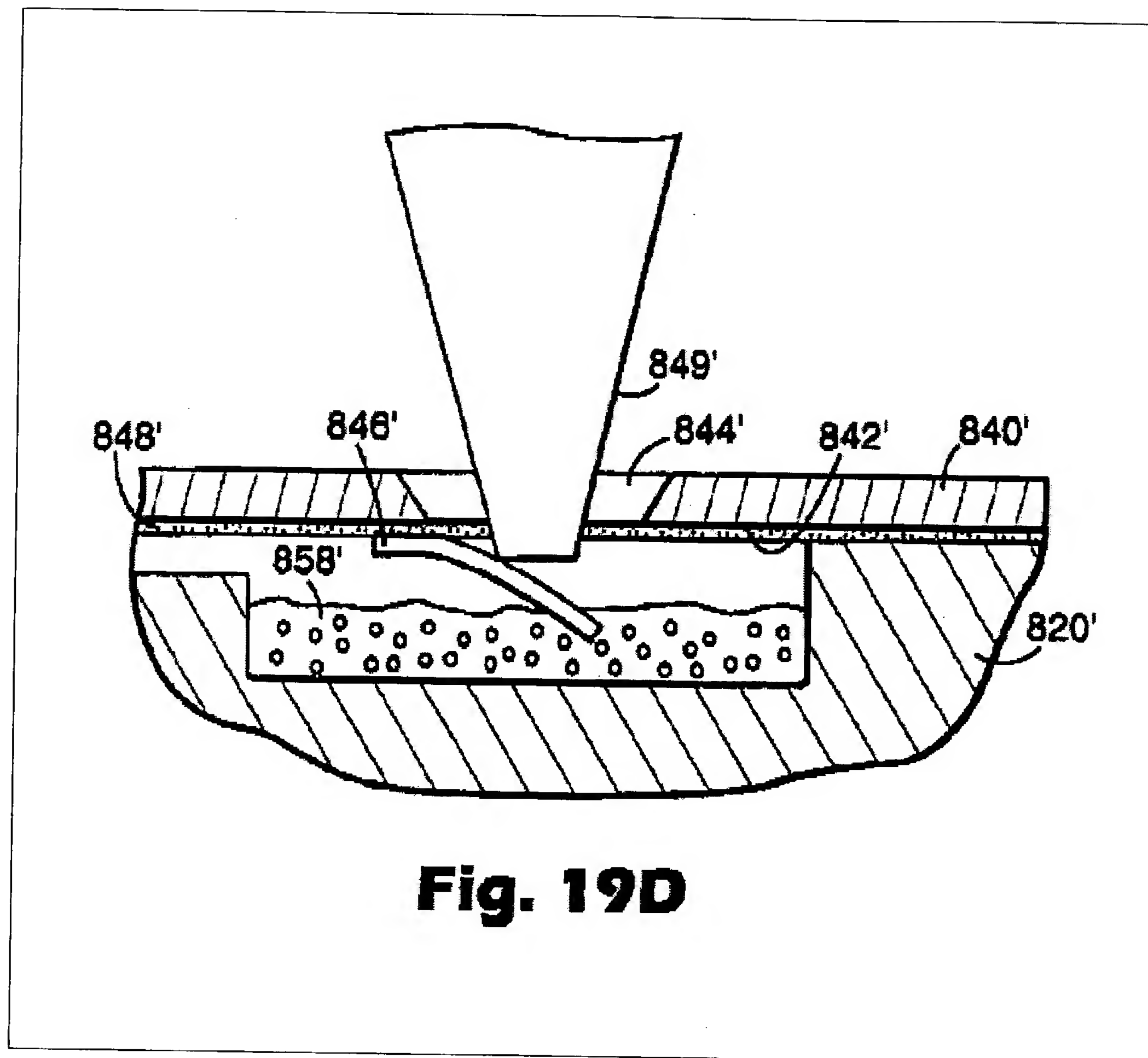
Fig. 4

As evidenced by Peters, a person of ordinary skill in the art would have recognized the suitability of incorporating the use of wedge-shaped cut-out structures within a microfluidic apparatus for the intended purpose of facilitating effective fluid control (see MPEP § 2144.07). Consequently, a person of ordinary skill in the art would accordingly have had a reasonable expectation of success of incorporating the use of these wedge-shaped cut-out structures within a microfluidic apparatus for facilitating effective fluid control. The Courts have held that the prior art can be modified or combined to reject claims as *prima facie* obvious as long as there is a reasonable expectation of success. See *In re Merck & Co., Inc.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986) (see MPEP § 2143.02). Therefore, it would have been obvious to a person of ordinary skill in the art to incorporate the use of wedge-shaped cut-out structures, as taught by Peters, with the microfluidic apparatus disclosed by Columbus '029 in order to provide an effective for effective sample fluid control within the microfluidic apparatus.

Regarding claims 5 and 6, as shown in figure 3b, these cylindrical or columnar projections (9) comprise essentially post structures, which extend from the base-plate (8), having wedge-shaped cut-outs (1) (see col. 5, lines 1 – 15).

2. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Columbus '029 in view of Bedingham et al. (U.S. Pat. No. 6,734,401 B2). Columbus '029 is silent to the specific teaching of incorporating an inlet port that is tapered to engage the corresponding shape of a pipette tip for depositing a sample fluid into the apparatus. Bedingham et al. do teach the incorporation of an inlet port (844') that is tapered to facilitate engagement with the corresponding shape of a pipette probe tip (849') for

permitting the introduction of a sample fluid into the disclosed apparatus (see col. 32, lines 19 – 61; figure 19D).



Hence, as evidenced by Bedingham et al., a person of ordinary skill in the art would have recognized the suitability of incorporating the use of a tapered inlet port with a microfluidic apparatus for the intended purpose of facilitating effective sample fluid introduction into the microfluidic apparatus (see MPEP § 2144.07). Furthermore, in view of the teachings of Bedingham et al., a person of ordinary skill in the art would accordingly have had a reasonable expectation of success of incorporating a tapered inlet

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with a microfluidic apparatus for facilitating effective fluid control. The Courts have held that the prior art can be modified or combined to reject claims as *prima facie* obvious as long as there is a reasonable expectation of success. See *In re Merck & Co., Inc.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986) (see MPEP § 2143.02). Therefore, it would have been obvious to a person of ordinary skill in the art to incorporate the use of a tapered inlet port, as taught by Bedingham et al., with the microfluidic apparatus of Columbus '029, for facilitating effective sample fluid transfer and control.

Conclusion

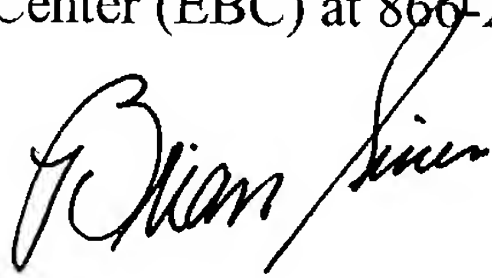
The prior art made of record and not relied upon is considered pertinent to applicant's disclosure: Columbus '399 further teaches a microfluidic device utilizing capillary flow. Barbera-Guillem teaches a microfluidic device comprising, inter alia, a tapered filling port and a vent aperture. McNeely et al. teach a microfluidic apparatus incorporating the use of a microchannel network and a passive valve system. Wyzgol et al. teach various structures utilized in controlling fluids within microfluidic devices.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian J. Sines, Ph.D. whose telephone number is (571) 272-1263. The examiner can normally be reached on Monday - Friday (11 AM - 8 PM EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read "G. Brian Sinner". The signature is written in a cursive, flowing style.